

Listing of Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

1.-29. (Canceled)

30. (Currently Amended) A pharmaceutically acceptable starch ~~especially~~ for parenteral administration, ~~preferably by way of injection~~, to a mammal, ~~especially a human~~, which

- a) has an amylopectin content in excess of 85 percent by weight, in which the molecular weight of said amylopectin has been reduced, ~~preferably~~ by shearing so that at least 80 percent by weight of the ~~material~~ starch lies within the range of 10-10,000 kDa; [,]
- b) has a purity of at most 50 µg amino acid nitrogen per gram dry weight of starch; [,] ~~and preferably at most 20 µg, more preferably at most 10 µg, and most preferably at most 5 µg, amino acid nitrogen per gram dry weight of starch~~
- c) can be dissolved in a concentration exceeding 25 percent by weight in water.

31. (Currently amended) A pharmaceutically acceptable starch ~~especially~~ for parenteral administration, ~~preferably by way of injection~~, to a mammal, ~~especially a human~~, which

- a) has an amylopectin content in excess of 85 percent by weight, in which the molecular weight of said amylopectin has been reduced, ~~preferably~~ by shearing so that at least 80 percent by weight of the ~~material~~ starch lies within the range of 10-10,000 kDa; [,]
- b) has a purity of at most 50 µg amino acid nitrogen per gram dry weight of starch; [,] ~~and preferably at most 20 µg amino acid nitrogen, more preferably at most 10 µg, and most preferably at most 5 µg, amino acid nitrogen per gram dry weight of starch~~
- c) lacks hydroxyethylation, ~~covalently bonded additional chemical groups of the type that occur in hydroxyethyl starch.~~

32. (Currently amended) [A] The starch according to claim 30 or claim 31, which exhibits the ability to gel *in vitro*.

33. (Currently amended) [A] The starch according to claim 31, which exhibits the ability to form microparticles in an emulsion system, ~~especially comprising~~ a two-phase aqueous system.

34. (Currently amended) [A] The starch according to claim 31, which has an endotoxin content of less than 35 EU/g and contains fewer than 100 microorganisms per gram.

35. (Canceled)

36. (Currently amended) [A] The starch according to claim 31, in which ~~said the~~ molecular weight of the amylopectin is within the range of 100 – 4000 kDa, ~~preferably 200—1000 kDa and more preferably 300—600 kDa.~~

37. (Currently amended) [A] The starch according to claim 31, which can be dissolved in water in a concentration exceeding 30% by weight, ~~preferably exceeding 40%, and more preferably exceeding 45%, by weight.~~

38. (Currently amended) [A] The starch according to claim 31, which remains in solution at a temperature of at most 60°C, ~~preferably 20-45°C, especially 30-37°C~~, for a period sufficiently long to allow combining with a substance that is temperature sensitive and/or unstable in organic solvents, ~~especially a protein.~~

39. (Currently amended) [A] The starch according to ~~claim~~ any one of claims 38, 57, or 58, wherein said combining is performed under [at] conditions which are able to retain the bioactivity of the ~~said~~ substance.

40. (Currently amended) [A] The starch according to claim 31, which, when dissolved in water, solidifies at a temperature of 1-55°C, ~~especially at 4-37°C.~~

41. (Currently amended) [A] The starch according to claim [40] 31, which solidifies when exposed to an initial temperature of 1-10°C, ~~especially about 4°C~~, and subsequently to a subsequent temperature [of] selected from 20-25°C, preferably or 25-40°C, ~~especially about 37°C.~~

42. (Currently amended) Microparticles based on starch as a carrier for a biologically active

substance, ~~especially~~ for parenteral administration, ~~preferably by way of injection~~, to a mammal, ~~especially a human~~, in which said starch is the starch as defined in claim 31.

43. (Currently amended) Microparticles according to claim 42, which have a mean particle diameter in the range of 10-200 μm , ~~preferably 20-100 μm , especially 20-80 μm .~~

44. (Currently amended) Microparticles according to claim 42, which exhibit the ability to be dissolved by enzymatic action ~~in vitro~~ in vitro or eliminated from biological tissue ~~in vivo~~ in vivo.

45. (Previously presented) Microparticles according to claim 42, in which the biologically active substance is a protein.

46. (Canceled)

47. (Currently amended) A starch having a purity of at most 50 μg amino acid nitrogen per gram dry weight of starch and an endotoxin content of less than 25 EU/g and containing fewer than 100 microorganisms per gram, said starch being pharmaceutically acceptable for injection into a human being and obtainable by a process starting from starch in solid form with an amylopectin content in excess of 85 percent by weight expressed as dry weight of starch comprising the following steps:

- (a) subjecting said solid starch to one or more washings ~~washing(s)~~ under conditions such that material comprising proteins, lipids and endotoxins surface-localized on the starch, as well as more sparingly soluble proteins, are dissolved while the starch remains undissolved, and separating the starch from the dissolved material, said one or more washings comprising a washing with an aqueous alkaline solution for dissolving said water-soluble proteins, lipids and endotoxins and a washing with an aqueous solvent with the ability to dissolve zein for dissolving said more sparingly soluble proteins[,];
- (b) causing the washed starched obtained from step (a) to dissolve in an aqueous medium;
- (c) subjecting the starch solution to a molecular weight reduction by shearing such that a molecular weight distribution is obtained in which at least 80 percent

by weight of the material lies within the range of 10-10,000 kDa; and

(d) removing residual water-soluble proteins from the starch by subjecting the starch solution to ion exchange chromatography, said ion exchange chromatography being performed either before or after the shearing step (c), wherein the starch is pharmaceutically acceptable for injection into a human being.

48. (New) The starch according to claim 30 or claim 31, wherein parenteral administration is by injection.
49. (New) The starch according to claim 30 or claim 31, wherein the mammal is a human.
50. (New) The starch according to claim 30 or claim 31, wherein, in b), the starch has a purity of at most 20 µg amino acid nitrogen per gram dry weight of starch.
51. (New) The starch according to claim 30 or claim 31, wherein, in b), the starch has a purity of at most 10 µg amino acid nitrogen per gram dry weight of starch.
52. (New) The starch according to claim 30 or claim 31, wherein, in b), the starch has a purity of at most 5 µg amino acid nitrogen per gram dry weight of starch.
53. (New) The starch according to claim 31, in which, in a), the molecular weight of the amylopectin is within the range of 200-1000 kDa.
54. (New) The starch according to claim 31, in which, in a), the molecular weight of the amylopectin is within the range of 300-600 kDa.
55. (New) The starch according to claim 31, which can be dissolved in water in a concentration exceeding 40% by weight.
56. (New) The starch according to claim 31, which can be dissolved in water in a concentration exceeding 45% by weight.

57. (New) The starch according to claim 31, which remains in solution at a temperature of at most 20-45°C, for a period sufficiently long to allow combining with a substance that is temperature sensitive and/or unstable in organic solvents.

58. (New) The starch according to claim 31, which remains in solution at a temperature of at most 30-37°C, for a period sufficiently long to allow combining with a substance that is temperature sensitive and/or unstable in organic solvents.

59. (New) The starch according to any one of claims 31, 57, or 58, in which the substance that is temperature sensitive and/or unstable in organic solvents is a protein.

60. (New) The starch according to claim 40, which, when dissolved in water, solidifies at a temperature of 4-37°C.

61. (New) The starch according to claim 41, which solidifies when exposed to an initial temperature of 4°C, and to a subsequent temperature of 37°C.

62. (New) The microparticles according to claim 42, which are parenterally administered by injection.

63. (New) The microparticles according to claim 43, which have a mean particle diameter in the range of 20-100 µm.

64. (New) The microparticles according to claim 43, which have a mean particle diameter in the range of 20-80 µm.